

Bard Medical Division
C. R. Bard, Inc.
8195 Industrial Blvd.
Covington, GA 30014



NOV 2 2012

Section 6: 510(k) Summary

The following information is provided as required by 21 CFR §807.92 for the Ajust® Helical Adjustable Single-Incision Sling Special 510(k) premarket notification. In response to the Safe Medical Devices Act of 1990, the following is a summary of the safety and effectiveness information upon which the substantial equivalence determination is based.

Sponsor: BARD Medical Division
C. R. BARD, Inc.
8195 Industrial Blvd.
Covington, GA 30014

Contact: Michele Davis, RAC
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C. R. Bard, Inc.
8195 Industrial Blvd.
Covington, GA 30014
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Submission Date: October 5, 2012

Proprietary Name: Ajust® Helical Adjustable Single-Incision Sling

Common Name: Surgical Mesh

Regulation: 21 CFR §878.3300

Regulatory Class: II

Product Code: PAH - Mesh, Surgical, Urogynecologic, For Stress Urinary
Incontinence, Female, Single-Incision Mini-Sling

Predicate Device(s): Ajust® Adjustable Single-Incision Sling – K092607

Device Description:

The Ajust® Helical Adjustable Single-Incision Sling System is a sterile, single use procedure kit that consists of a mesh sling implant and instruments, flexible stylet and two helical shaped introducers, which aid in the placement of the mesh in the

pelvic floor. The product is offered in a single kit and dispenser pack of 5 individual kits.

SIOS: The sling implant is composed of four primary components – polypropylene flat mesh, polypropylene tube mesh, polypropylene anchors and a polypropylene sling lock. The adjusting tab is only used during adjustment and is not part of the permanent implant. The flexible stylet is a thin, flexible, Nitinol wire that allows the stylet to conform and flex to follow the path of the tube mesh to push the sling lock into position. The stainless steel helical shaped introducers allow for placement of the anchors in the obturator membrane/muscle by rotation of the handle of the introducer.

Intended Use:

The Ajust® Helical Adjustable Single Incision Sling is indicated for the treatment of female stress urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

Summary of the Technological Characteristics Comparison to Predicate Device:

The Ajust® Helical Adjustable Single-Incision Sling System has the same intended use and fundamental scientific technology as the predicate device. The only difference between the predicate device and the proposed device is the shape of the introducer offered in the kit. The predicate device has a hook shaped introducer and the proposed device has an introducer with a helical shape. The modification to the Ajust Helical Adjustable Single-Incision Sling System is deemed equivalent to the current device, Ajust Adjustable Single-Incision Sling.

Performance Data Summary:

The modified introducers of the Ajust® Helical Adjustable Single-Incision Sling have been tested for design verification and validation. Design verification and/or validation testing of the helical introducers included the following tests:

- Introducer compression and side load strength
- Weld strength of the introducer cannula to cannula plate

- Introducer handle pull apart strength
- Introducer collet retention of anchor
- Introducer collet release of anchor
- Anchor placement
- Biocompatibility testing

The product performance of the Ajust® Helical Adjustable Single-Incision Sling is substantially equivalent to the Ajust® Adjustable Single-Incision Sling.

Substantial Equivalence:

The Ajust® Helical Adjustable Single-Incision Sling has the same indications for use and fundamental scientific technological characteristics as the predicate device. Based on this, the design and the summary of design control activities provided in this submission, the proposed Ajust® Helical Adjustable Single-Incision Sling has been shown to be substantially equivalent to the cleared Ajust® Adjustable Single-Incision Sling.

Conclusions:

The modified device, Ajust® Helical Adjustable Single-Incision Sling, is substantially equivalent to the predicate device, Ajust® Adjustable Single-Incision Sling.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Letter Date: November 2, 2012

C. R. Bard, Inc.
% Ms. Michele Davis, RAC
Regulatory Affairs Project Manager
8195 Industrial Blvd.
COVINGTON GA 30014

Re: K123179
Trade/Device Name: Ajust® Helical Adjustable Single-Incision Sling
Regulation Number: 21 CFR§ 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: PAH
Dated: October 5, 2012
Received: October 9, 2012

Dear Ms. Davis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

 Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 5: Indications for Use Statement

510(k) Number (if known): K123179

Device Name: Ajust® Helical Adjustable Single-Incision Sling

Indications for Use:

Ajust® Helical Adjustable Single-Incision Sling is indicated for the treatment of female stress urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Benjamin R. Fisher -S
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(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and
Urological Devices
510(k) Number K123179

Page 1 of 1

Special 510(k) Submission for the Ajust® Helical Adjustable Single-Incision Sling

Page 17 of 38